

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/500,463

INTERNATIONAL APPLICATION NO.
PCT/JP03/00251

INTERNATIONAL FILING DATE
15 January 2003

PRIORITY DATE CLAIMED
16 January 2002

TITLE OF INVENTION
PHARMACEUTICAL COMPOSITION COMPRISING 2,2-DICHLORO-12-(4-CHLOROPHENYL)-DODECANOIC ACID

APPLICANT(S) FOR DO/EO/US
Shin-ichiro KOBAYASHI, Niichiro TAKANO, Hiroyuki KAWASHIMA, Yasuo SHINODA, and Toshio INAGI

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.

1. ☐ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (23) indicated below.
4. ☐ The US has been elected (PCT Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154 (d) (4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
"Executed"
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 22 below concern other document(s) or information included:

11. Assignee: KOWA COMPANY, LTD., of Aichi, Japan
12. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
13. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
14. ☐ A FIRST preliminary amendment.
☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ An Application Data Sheet under 37 C.F.R. 1.76.
16. ☐ A substitute specification.
17. ☐ A power of attorney and/or change of address letter.
18. ☐ Figure of Drawing to be published:
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154 (d) (4).
21. ☐ A second copy of the English language translation of the international of the international application under 35 U.S.C. 154 (d) (4).
22. ☒ Other items or information:
Cover Letter.
Copy of Form PCT/DO/EO/905 (Notification of Missing Requirements).
Completion of Record, with attached International Preliminary Examination Report (form PCT/IPEA/409).

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/500,463		PCT/JP03/00251		P25616	
23 <input type="checkbox"/> The following fees are submitted: Basic national fee.....300.00				CALCULATIONS	PTO USE ONLY
				\$ 0.00	
24 <input type="checkbox"/> Examination Fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33 (1)-(4).....100.00 All other situations.....200.00				\$ 0.00	
				25 <input type="checkbox"/> Search fee Search fee (37 CFR 1.445(a) (2)) has been paid on the international application to the USPTO as an International Searching Authority.....100.00 International Search Report prepared and provided to the Office.....400.00 All other situations.....500.00	
TOTAL 23, 24 and 25 =					
<input type="checkbox"/> Additional Fee for Specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in electronic medium). The fee is \$250.00 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
-100=	/50 =		x \$250.00	\$ 0.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				\$130.00	
Claims	Number Filed	Number Extra	Rate		
Total Claims	4 - 20 =	0	x \$50.00	\$ 0.00	
Independent Claims	3 - 3 =	0	x \$200.00	\$ 0.00	
Multiple Dependent Claim(s) (if applicable)			+ \$360.00	\$ 0.00	
TOTAL OF ABOVE CALCULATIONS =				\$130.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ 0.00	
SUBTOTAL =				\$130.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (i)).				\$ 0.00	
Extension of Time fee in the amount of \$				\$ 0.00	
TOTAL NATIONAL FEE =				\$130.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ 0.00	
TOTAL FEES ENCLOSED =				\$130.00	
				Amount to be refunded	\$
				Charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$130.00 to cover the above fees is included. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. c. <input checked="" type="checkbox"/> The U.S. Patent and Trademark Office is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0089. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status. SEND ALL CORRESPONDENCE TO CUSTOMER NO. 07055 AT THE PRESENT ADDRESS OF:					
Bruce H. Bernstein GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clark Place Reston, VA 20191 (703) 716-1191			Stephen M. Roylance Reg. No. 31,296		
			SIGNATURE		
			Bruce H. Bernstein		
			NAME		
			29,027		
			REGISTRATION NUMBER		

07/29/2005 GFREY1 00000084 10500463

01 FC:1617 130.00 DP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Shin-ichiro KOBAYASHI et al. **Mail Stop PCT**
Appl. No: : 10/500,463 (National Stage of PCT/JP03/00251)
I. A. Filed : July 14, 2004
For : PHARMACEUTICAL COMPOSITION COMPRISING 2,2-DICHLORO-
12-(4-CHLOROPHENYL)-DODECANOIC ACID

COVER LETTER

Mail Stop PCT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop PCT
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In order to comply with the requirements (copy enclosed) for the submission of an executed Declaration of the International Application set forth in the Notification mailed May 26, 2005 which sets a two-month period of response until July 26, 2005, Applicants hereby submit:

- Transmittal Letter to the United States Designated/Elected Office Concerning a Filing Under 35 U.S.C. 371;
- an executed Declaration and Power of Attorney; and
- a check in the amount of \$130.00 to cover the surcharge for late filing of the Declaration.


Also enclosed is:

- a Completion of Record, with attached International Preliminary Examination Report.

The U.S. Patent and Trademark Office is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 19-0089.

Should the Examiner have any questions, he is invited to contact the undersigned at the below-listed number.

Respectfully submitted,
Shin-ichiro KOBAYASHI et al.



Bruce H. Bernstein
Reg. No. 29,027

Stephen M. Roylance
Reg. No. 31,296

July 5, 2005
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/500,463	Shin-ichiro Kobayashi	P25616

INTERNATIONAL APPLICATION NO.

PCT/JP03/00251

7055
 GREENBLUM & BERNSTEIN, P.L.C.
 1950 ROLAND CLARKE PLACE
 RESTON, VA 20191

RECEIVED

MAY 31 2005

GREENBLUM & BERNSTEIN PLC

I.A. FILING DATE

PRIORITY DATE

01/15/2003

01/16/2002

CONFIRMATION NO. 5292
 371 FORMALITIES LETTER
 OC000000016136128
 OC000000016136128

Date Mailed: 05/26/2005

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 07/14/2004
- Copy of the International Search Report filed on 07/14/2004
- Copy of IPE Report filed on 07/14/2004
- Oath or Declaration filed on 07/14/2004
- Request for Immediate Examination filed on 07/14/2004
- Copy of references cited in ISR filed on 07/14/2004
- U.S. Basic National Fees filed on 07/14/2004
- Priority Documents filed on 07/14/2004

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
 - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Late oath or declaration Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

PATRICIA A BOOKER

Telephone: (703) 308-9140 EXT 204

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/500,463	PCT/JP03/00251	P25616

P25616.A03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Shin-ichiro KOBAYASHI et al. Group Art Unit : 1614
Appl. No. : 10/500,463
(U.S. National Phase of PCT/JP03/00251) Examiner : Not Yet Assigned
Filed : July 14, 2004 Confirmation No.: 5292
For : PHARMACEUTICAL COMPOSITION COMPRISING 2,2-DICHLORO-12-(4-CHLOROPHENYL)-DODECANOIC ACID

COMPLETION OF RECORD

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop AMENDMENT
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir :

To complete the record, applicants bring to the Examiner's attention an International Preliminary Examination Report in English dated May 19, 2005, with respect to International Patent Application No. PCT/JP03/000251, in which no new documents were cited.

Applicants respectfully request that the Examiner consider the International Preliminary Examination Report. A copy of the International Preliminary Examination Report is attached.

Should the Examiner have any questions, the Examiner is invited to
contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
Shin-ichiro KOBAYASHI et al.

A handwritten signature in black ink, appearing to read "Bruce H. Bernstein".

Bruce H. Bernstein
Reg. No. 29,027

Stephen M. Roylance
Reg. No. 31,296

June 15, 2005
GREENBLUM & BERNSTEIN, P.L.C.
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